Exhibit H

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MASTER FILE NO. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

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The Document Relates to:
Constance Daino v. Ethicon, Inc.
Case No. 2:12-cv-01145

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DEPOSITION OF SHELBY F. THAMES, Ph.D.

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Taken at Butler Snow
1020 Highland Colony Parkway, Suite 1400,
Ridgeland, Mississippi,
on Thursday, March 24, 2016,
beginning at approximately 2:43 p.m.

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AMY M. KEY, RPR, CSR
Notary Public

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E X H I B I T S

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S T I P U L A T I O N

It is hereby stipulated and agreed by respective attorneys of record, that this deposition may be taken at the time and place hereinbefore set forth, by AMY M. KEY, Court Reporter and Notary Public, pursuant to the Rules;

That the formality of reading and signing is specifically RESERVED;

That all objections, except as to the form of the questions and the responsiveness of the answers, are reserved until such time as the deposition, or any part thereof, may be used or sought to be used in evidence.

****

SHELBY F. THAMES, Ph.D.,
having been first duly sworn,
was examined and testified as follows:

EXAMINATION

BY MR. BOWMAN:

Q. So, Doctor, it's me again, Mike Bowman. I haven't handed you an exhibit. But you have a report in front of you. Who is it for?

A. It's for Constance Daino.

MR. BOWMAN: Could we mark that as an Exhibit 1 to this deposition, please?

(EXHIBIT NO. 1 MARKED.)

BY MR. BOWMAN:

Q. So, Doctor, have you seen this report before?

A. Yes, sir, I wrote it.

Q. Did you have a chance to review it before the deposition began?

A. Briefly.

Q. Have you ever met Ms. Daino?

A. No, sir.

Q. Do you know if I am pronouncing her last name correctly?

A. I do not know, sir. I'm hoping I am.

Q. I believe it's Daino. As I understand it,

you finalized this report on March 22nd; is that right?

A. Yes, sir.

Q. And you also, as in the Stubblefield case, worked with Dr. Kevin Ong at Exponent Labs; is that correct?

A. I did, sir.

Q. And everything you testified to with respect to your working relationship with Dr. Kevin Ong previously, did that hold true in this case as well?

A. Yes, it does.

Q. Do you know were there -- is there anything that sticks out to you about the protocol used in this case that didn't hold true in the Stubblefield case?

A. The protocol, no, but the sample was different.

Q. The sample was different?

A. Yeah. It was dry when we received it.

Q. Can you explain that?

A. It was not in formaldehyde, and so there were decomposition products, as was the case with Ms. Stubblefield.

Q. Ms. Stubblefield was dry as well?

A. No. When we got it, it was in formaldehyde. But the fact that it had these decomposition products meant at some point in time, between the time the explant had got to me, it had to be dry at some point because of the decomposition products.

Q. Do you have any idea when that might have happened?

A. No, sir.

Q. Not with respect to Ms. Stubblefield, but with respect to Ms. Daino?

A. No, sir, I don't know.

Q. So Ms. Daino's mesh came to you in a dry format --

A. Yes, sir.

Q. -- with tissue attached?

And your light microscopy photo in figure 3 is representative of how you found it?

A. Yes, sir.

Q. Now, you didn't take this photo?

A. No, sir, my associate did.

Q. And just to talk again about what we talked about in the last deposition, the figure 2 pristine TVT mesh, do you see that?

A. Yes, sir.

Q. Do you know if that's a laser cut mesh or a mechanically cut mesh?

A. As we stand here today, I don't know, but I could probably find out if I went through the documents.

Q. Does it look like a laser cut mesh to you?

A. It's hard to say, sir, from the -- I cannot be definitive.

Q. Okay. With respect to this laser cut mesh, is it your understanding that it went through the same cleaning process as the mesh that -- as Ms. Daino's mesh went through?

A. Yes.

Q. And by that, of course, I mean that it went through five cleaning processes as Ms. Daino's mesh did?

A. Yes, sir.

Q. If we look at figure 4, you did 100 times magnification?

A. Yes, sir.

Q. And this is under light microscopy; is that correct?

A. Yes, sir.

Q. And this is of the mesh as it was produced to you; is that correct?

A. It was before cleaning, and it's a beautiful -- it shows a lot of stuff.

Q. What does it show?

A. Well, if you'll look at the -- this area right here (indicating), that is protein material that was on the surface of the explant, and it's peeled back. And you notice right here at the bottom, I'm pointing at the bottom to the -- the almost bottom fiber on the far left, the same thing is here, and that's a classical example of what we're seeing for this material that's on the surface of Prolene. Now, this is before anything has been done to it.

Q. I understand.

A. And what we're going to find out is once this is put through the first washing step, cleaning step, that will disappear because it's so fragile.

Q. So looking at this photograph in figure 4, do you notice that in the direct center, down here --

A. Yes, sir.

Q. -- that it appears that the protein has been disturbed?

A. Yes. It's coming off the fiber.

Q. So, actually, that's not what I'm looking

at. I'm looking at the jigsaw puzzle aspect of the protein. So it looks like there's a protein sheath there, and it's been disturbed either by your photographer or in shipping.

Do you see how they connect together?

A. Well, to some degree, but not -- I also see how, if this is laid back over this fiber, it would have been right here where my little small finger is pointing, which it's hard to, obviously, say on the telephone and what else. But it could have been laid back this way, and this would be this way, right in this clear area right here and this clear area right here.

Q. Do you think your associate disturbed that protein on purpose or that layer of tissue or whatever that is on purpose?

A. No, sir. I think that's the way it came to us. It had been -- obviously, it was disturbed because it was received from the hospital. It was transmitted down to Kevin Ong's lab. He put it in a different container. He had washed it, and he sent it down to us.

Q. Can I see the exhibit for a second?

A. Sure.

Q. I'm just going to circle the portion that

I was asking you to look at as far as the jigsaw nature of it.

Do you see what I'm marking as being disturbed on this?

A. I do.

Q. So do you agree with me that at some point that was connected or seems to be at some point that was all one larger piece of protein or tissue?

A. I can't say. There's a possibility that it was, but I can't say for sure that it was.

Q. Do we see the same thing -- if you just look directly above it, it looks like there's sort of the same thing going on there. There's like a matrix of collagen or tissue, and there's some see-through portions of it?

A. Yeah, it's translucent material that we're talking about, right.

Q. I think so. If that's what you're calling it, yes. To me, it sort of looks like a thin layer of collagen or protein or something like that.

With respect to this mesh, does anything else jump out at you?

A. No, sir, not really.

Q. Okay. How about the fact there's no blue filaments?

A. Well, it's an all-clear mesh.

Q. So this would have been implanted prior to 2003 or something like that?

A. Yes, sir, right. I think it was 2003. And I think, if I remember, they started using colored mesh in like 2003, 2000 and 2003. So this could have been something that had on -- and I don't know. I'm speculating here that there might have been some that they had reserved that hadn't been used before.

Q. With respect to the second full paragraph on this page, which is page 4, it states -- you talk about patient 4 from your general report.

Do you see that?

A. Yes, I do.

Q. And it talks about -- and patient 4 had blue pigmented material, correct?

A. Yes, sir.

Q. And you actually make the reference that both clear Prolene and pigmented Prolene are translucent under light microscopy.

Do you see that?

A. I do.

Q. Is there any statement in here that Ms. Daino -- let me see this. So this entire

paragraph is in reference to patient 4. This is not in reference to Ms. Daino at all?

A. That's essentially correct, yes, sir.

Q. So you're not saying anything about any findings that you made on Ms. Daino's mesh in this paragraph?

A. I'm giving an example of what we had done before on patient 4.

Q. That doesn't -- does that have any --

A. Not directly to --

Q. Ms. Daino?

A. Ms. Daino, yes.

Q. Okay. Thank you.

With respect to figure 5, --

A. Yes, sir.

Q. -- do you see any flakes or bark hanging off of the figure itself?

A. Yes. But there's more flesh here than -- see, what we were looking at before in figure -- well, before cleaning was material that hadn't been cleaned at all. Now then, it has been cleaned a step, and we see that we have disturbed some of the flesh around the fibers. We're seeing more of the fibers, and we're also seeing some flaking. You can see it here. Obviously --

Q. Can you mark it?

A. Obviously, the flakes won't be as long and prominent because they've been through a cleaning step.

Q. Can you mark where you see some flakes, please?

A. Sure. It's a little difficult to find here because we've still got flesh on it.

Q. So with respect to figure 5, I can see at least three or four portions where it's not clear?

A. That's correct.

Q. Do you see those?

A. Yes.

Q. So just seeing those alone is something that would -- you would take the FTIR, do the light microscopy, do the SEM.

Would you do SEM at this point?

A. Yes, sir.

Q. And then you would send it back to Kevin Ong, correct?

A. Yes, sir.

Q. For more cleaning?

A. Yes, sir.

Q. But your determination wouldn't have been made on sending it back to Kevin Ong until you saw

the results of the FTIR, SEM and light microscopy?

A. That's right.

Q. Okay. So getting into the next page, there's a reference to blue fiber again?

A. Yes, sir.

Q. And this one appears to actually reference it with Ms. Daino.

A. Where are we, sir?

Q. Sure. Page 5, the section entitled, "Chemical Structure Analysis by FTIR Spectroscopy."

A. What paragraph?

Q. The very first one.

So the second sentence reads, "The layer on the blue fiber is clear, not blue, again confirming its composition is not Prolene. If it were degraded Prolene, it would be blue, and it is not."

Do you see that?

A. Yes.

Q. Does that belong in this report?

A. Well, it's used there as a comparison.

Q. Okay.

A. The clear fiber is -- you can make a comparison when you have a blue and a clear. And I wanted to make the comparison between patient 4,

which we talked about earlier today, which was Ms. Ramirez, and so I use that here as a comparison, that the blue fiber in Ms. Ramirez was translucent material, just like the material here is translucent material. Neither her translucent material was blue, as this is not blue.

Q. So way the sentence reads, "The layer in the blue fiber is clear, not blue, again confirming its composition is not Prolene."

A. Right.

Q. And then it says, "Daino 1.1," and that's figure 5?

A. Well, that was meant to be Ms. Ramirez. I guess I made a mistake here. Let me check it out. This is clear fiber.

Oh, I say in the first sentence, "It's also important to note the identical translucent nature of the cracked and peeling material on both the blue and clear fibers as shown in patient 4, examples in my general report. The layer on the blue fiber is clear, not blue, again confirming its composition is not Prolene, Daino 1.1, comparatively speaking."

Q. So, again, I don't see any flaking, and I don't see any blue on Ms. Daino's.

A. There is none. I'm trying to draw a comparison between Ms. Ramirez and Ms. Daino, so that's the only thing I'm trying to do here.

Q. Okay. Without blue fibers?

A. That is correct, sir.

Q. Anywhere in this report is there a photo from patient 4?

A. Let me see. No, sir.

Q. So with respect to the first paragraph and the second paragraph, you are merely referencing this case-specific report back to your general causation report; is that right?

A. Yes, sir.

Q. And there is nothing specific that you can relate with with blue fibers or with any kind of photograph showing translucent blue fibers -- translucent cracks in blue fibers to Ms. Daino; is that correct?

A. It was used only as an example.

Q. The next paragraph, it goes to -- it starts describing the FTIR in figure 6.

Do you see that?

A. Yes.

Q. And in figure 6 we see that there is -- there are bumps and valleys in between the area of

3000 and 3600.

Do you see that?

A. Yes, sir.

Q. And that's the general area where a carboxyl group would be?

MR. HUTCHINSON: Object to form.

THE WITNESS: In that general area, yes, sir.

BY MR. BOWMAN:

Q. And with respect to the area between 1650 and 1750, we do see at least two peaks and maybe one broad range, and this is an area where we would expect to see carbonyls; is that correct?

A. Well, you see two carbonyls, one is -- and the two peaks, the one at 15 and 16, are representative of proteins. And the 1654 is representative of the carbonyl group frequency of the proteins. And the 1741 is representative of decomposition products that we talked about earlier, because we received this explant dry. And, here again, we see the 1741 peak.

Q. Besides your knowledge of knowing that these peaks and valleys overlap between the hydroxyl group and carbonyl group --

A. Now, wait a minute. That's not correct.

Q. I'll repeat the question. Go ahead.

MR. HUTCHINSON: I don't think there's a question pending.

BY MR. BOWMAN:

Q. I'll withdraw the question, and I'll reask.

A. Okay. Thank you.

Q. With respect to the peaks in the 1650 to 1750 range that you just identified as having to do with decomposition and amide groups; is that right?

A. The 1654 peak is the C=O of the amide group, A-M-I-D-E. The 1741 is an ester peak coming from a decomposition product.

Q. Now, besides the fact that you know that that's where a carbonyl would show up, isn't this also where a carbonyl would show up on oxidized polypropylene?

A. That could be the same reason, yes, sir.

Q. And with this sample you -- with this sample, was any care taken to preserve any oxidized polypropylene that might be on the mesh?

A. The cleaning protocol itself was a caretaking process to try to make certain that what's on the explant when we received it was on the explant when we looked at it the last time, with the

exception of proteins.

Q. Now, can the same be said with respect to the carboxyl groups between the area of 3000 and, say, 3600?

A. Yes.

Q. And the --

A. No. Wait a minute. You said carboxyl groups? You're getting your chemistry wrong.

Q. I am. So the hydroxyl group between the area of, say, 3000 and 3600?

A. In that range, yes, sir.

Q. By hydroxyl group, can you tell me -- well, what do you understand a hydroxyl group to be?

A. A COH.

Q. And what do you understand a carbonyl to be?

A. A C=O.

Q. And the cleaning protocol itself didn't run oxidized polypropylene through it, did it, as a control?

That didn't happen?

A. No, sir.

Q. With respect to any other part of the cleaning process, was oxidized polypropylene used?

A. Now, you're talking -- you keep talking

about oxidized polypropylene.

Do you really mean that?

Q. What I mean to say is --

A. I didn't use polypropylene.

Q. You used Prolene?

A. I used Prolene.

Q. What I mean to say is that for any one of the steps, we're talking about the -- let's just stick with the Proteinase K.

Did you put -- did you purposefully oxidize Prolene and then put it through that step of the cleaning process?

A. No, sir.

Q. And did you do that with any of the steps of the cleaning process?

A. No, sir.

Q. But you did use pristine Prolene as a control, and you did use a pristine Prolene sample in Ms. Daino's case, TVT mesh?

A. Yes, sir, that's correct.

Q. And you ran that through the cleaning process?

A. That's correct.

Q. With respect to figure 7, --

A. Yes, sir.

Q. -- that is the before cleaning tissue between fibers --

A. Yes, sir.

Q. -- overlaid in red?

And then the collagenase, Type VII, high purity, this is just like a textbook examplar as overlaid in blue?

A. Yes, sir.

Q. Can you tell me -- what do you see at 1742?

A. The purpose of that spectra was to show you the peak at 1742 was in the tissue between fibers, but not in collagenase, and that's the -- so it's not unique to collagenase, so it has to be unique to something else. And that means it's unique to the tissue sample itself.

Q. So this tissue sample --

A. It's not proteins.

Q. Right.

So this sample itself came to you decomposed?

A. Yes, sir.

Q. Almost entirely?

MR. HUTCHINSON: Object to form.

THE WITNESS: Well, it was decomposed.

I don't know to what extent it was decomposed.

BY MR. BOWMAN:

Q. It wasn't -- I'll strike the question.

It wasn't preserved in any way?

A. When we received it, it was not preserved. I cannot tell you what happened to it prior to our receiving it or Dr. Ong.

I could ask Dr. Ong what happened before he picked it up -- when he picked it up. But before that, I don't know who had it, for how long or what they did with it.

Q. Would this figure, figure 7, have been more instructive if you had laid in the background instead of collagenase some kind of collagen that had been decomposed, an FTIR of that?

A. No, I don't think so. No, sir, I don't believe so.

Q. My question is just simply then that would just tell me immediately that 1742 is decomposed collagen?

A. Well, this tells you it is because the protein is a carbonyl group itself, and it's right next to it. It has a carbonyl group in it itself, and that's at 1654. We talked about that just a few

seconds ago. And then you have another carbonyl group that's showing up at a different frequency.

So no, sir, to answer your question.

Q. With respect to figure 8, --

A. Yes, sir.

Q. -- you had the before cleaning clear fiber, and then you have the before cleaning tissue between fibers; is that correct?

A. Yes, sir.

Q. And the peaks appear to be the same.

And this is just what you were saying. The peaks appear to be the same, but they are at a much higher concentration in the between fibers, aren't they?

MR. HUTCHINSON: Object to form.

THE WITNESS: Yes, they are, as you would expect them to be. Because this is decomposition of the tissue that's taking place, which is between the fibers, not Prolene.

BY MR. BOWMAN:

Q. I get the answer.

With respect to the hydroxyl groups, why -- you know, I'm going to strike that question.

Moving on to figure 9, this is the figure

that encompasses all of the FTIRs that you took for this mesh; is that correct?

A. Yes, sir, from before cleaning to after step five.

Q. Now, with respect to the -- if we just look at after cleaning five, which appears to be gold, it has the lowest ranges possible.

It appears to have the lowest ranges possible out of all of the FTIRs; is that correct?

A. It shows you how effective our cleaning process was, yes, sir.

Q. And that cleaning process is directed by you to send it back to get more cleaning?

A. After cleaning five, I keep the explants.

Q. So just at five, you wouldn't have gone any further than what is in yellow; is that right?

A. That is correct, sir. And the reason is shown on the next page.

Q. If we go to the next page and we look at figure 10, it shows that the TVT exemplar, FTIR, clear fibers after cleaning steps; is that right?

A. Yes, sir, and they're identical.

Q. They appear to be identical.

Is there anywhere in the -- do you see a carbonyl peak here in the blue?

A. No, sir.
Q. So the TVT exemplar after cleaning five --
A. It's not supposed to have a carbonyl group, sir. It doesn't have a carbonyl on it. It didn't oxidize.
Q. But this is a different part of the TVT exemplar that you looked at, though, right?
You didn't look at the same -- you didn't do the FTIR on the same exact spot on every --
MR. HUTCHINSON: Object to form.
Compound question.
BY MR. BOWMAN:
Q. Do you want me to withdraw the question? I'll withdraw the question.
A. Thank you.
Q. And what I'll ask is, did you do FTIR on the TVT exemplar after every cleaning that was done?
A. Yes, sir.
Q. And where is that data?
A. We just looked at them, sir, right here (indicating).
Q. This is after cleaning. This is not the exemplar, though. This is of the mesh.
A. Well, they are done. I'm sorry. We have them in our documentation somewhere. You have

those.

MR. HUTCHINSON: They have been produced to counsel already.

BY MR. BOWMAN:

Q. So there is quite a big peak, isn't there? You don't see a peak at 1740, 1750 on the TVT exemplar?

A. No, sir.

MR. HUTCHINSON: Object to form.

BY MR. BOWMAN:

Q. What do you see there?

A. Nothing. I see some noise perhaps. You know, I told you earlier that this is not a quantitative measurement. We talked about qualitative measurement. And this is, in my opinion, as close as you're going to be being identical in a qualitative spectra that you can achieve.

Q. But isn't the FTIR just on one portion of the --

A. Yes, sir. But it's not quantitative in terms of telling you the exact amounts of materials that are there. So if there's a slight difference in the peak height here, in the red, for instance, the clear microscopy spectra of that fiber, that

doesn't mean that it's not identical to the blue. It's just qualitative and not quantitative.

Q. That's my point. I don't see a peak in the one that you cleaned after the one that was explanted from Ms. Daino. I don't see --

A. I don't either. They look identical to me.

Q. Okay. But we're looking at the same figure, figure 10?

A. Yes, sir, we are.

Q. With respect to your SEM opinions again -- strike that.

With respect to your SEM opinions, do you have anything in a peer review literature that would support the opinion that the extrusion lines would degrade along with the outer surface of the Prolene fiber?

A. If there was oxidation of Prolene, it is my opinion that extrusion lines would be interfered with. They are not here. I have not seen that written in another document, is my belief.

And you can see the extrusion lines being maintained all the way from an SEM -- well, about one, but certainly three. And you can see the transverse cracking and extrusion lines are still

there.

And you see how difficult it is to get all the proteins off? You see these little portions there? That continues to be proteins on there. And then you see number five, and we've got a really clean spectra.

Q. You mean a clean image?

A. Yes, full micrograph spectra, clean image, yes, sir.

MR. BOWMAN: I'm done. I pass.

MR. HUTCHINSON: Just a quick break.

(A BREAK WAS TAKEN.)

MR. HUTCHINSON: We don't have any more questions. Thank you.

(CONCLUDED AT 3:15 P.M.)

CERTIFICATE OF COURT REPORTER

I, Amy M. Key, CSR, and Notary Public in and for the County of Lamar, State of Mississippi, hereby certify that the foregoing pages, under penalty of perjury, contain a true and correct transcript of the testimony of the witness, as taken by me at the time and place heretofore stated, and later reduced to typewritten form by computer-aided transcription under my supervision and to the best of my skill and ability.

I further certify that I placed the witness under oath to truthfully answer the questions in this matter under the power vested in me by the State of Mississippi.

I further certify that I am not in the employ of or related to any counsel or party in this matter, and have no interest, monetary or otherwise, in the final outcome of the proceedings.

Witness my signature and seal this the _____ day of_____, 2016.

_____

AMY M. KEY, CSR

My Commission Expires June 19, 2016

SIGNATURE OF WITNESS

I, _____, do solemnly swear that I have read the foregoing pages and that the same is a true and correct transcript of the testimony given by me at the time and place hereinbefore set forth, with the following corrections:

PAGE:	LINE:	SHOULD READ:	REASON FOR CHANGE:
_____	_____	_____	_____
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_____
(SIGNATURE)

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

_____
Notary Public